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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/010,050	11/09/2001	Paul O. Sheppard	97-38C1	7831

7590

03/03/2005

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EXAMINER

MITRA, RITA

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 03/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/010,050

Applicant(s)

PAUL SHEPPARD

Examiner

Rita Mitra

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 34-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 34-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 11/19/04
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Status of the Claims

Applicants' amendment and response to office action dated June 16, 2004, filed on November 19, 2004 is acknowledged. Claims 1-33 have been canceled. Claims 41 and 44 have been amended. Therefore, claims 34-51 are currently pending and are under examination.

Response to Remarks and Arguments

Claim Rejections - 35 USC § 101 (Non-statutory):

Rejection of claim 40 under 35 USC 101 is withdrawn in light of Applicants' remarks on page 5.

Claim Rejections - 35 USC § 112, First Paragraph:

The rejection of claims 34-51 under 35 U.S.C. 112, first paragraph, for the reasons set forth in the objection to the specification is withdrawn in light of applicants' remarks on pages 7-8.

Claim Rejections - 35 USC § 112, Second Paragraph:

The rejection of claims 35, 37, 39, 41, 44 and 51 under 35 U.S.C. 112, second paragraph, is withdrawn in view of Applicants' comments on pages 8-10 and amendment to claims 41 and 44.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title"

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Claims 34-51 stand/are rejected under 35 U.S.C. 101 because the claimed polypeptides are not supported by either a specific and substantial asserted utility or a well established utility because the specification fails to assert any utility for the claimed protein.

In response, applicants traverse the foregoing rejection and argue (pages 6-7) that the rejection is contrary to both the law and the USPTO's own examination guidelines.

Applicants' arguments have been considered but not found persuasive because in the instant case Applicants assert on page 25 of the specification that the pharmaceutical composition comprising purified Zsig46 would be useful in the prevention or treatment of conditions associated with chromosome 13q. Examples of many diseases have been listed but the specification does not indicate any correlation of the role of a Zsig46 composition to a specific disease treatment or prevention. Also, high expression of Zsig46 in thyroid tissue does not lead one to conclude that Zsig46 polypeptide would be useful in treatment or prevention of thyroid diseases (please see previous office action).

Applicants also urge at page 6 of the response, that upon reading the specification at page 25, lines 24-30, which states "...the zsig46 gene is located in close proximity to the endothelin-B receptor gene, which is one of the 13-linked susceptibility gene for Hirschsprung disease," one of skilled in the art would immediately appreciate that zsig46 has a specific, substantial and credible utility. It should be noted here, that only by location in close proximity to the endothelin-B receptor gene, one skilled artisan would not interpret that zsig46 gene should have the same role as of the one of chromosome 13-linked susceptibility genes have for Hirschsprung disease. The specification does not indicate any correlation of the role of a Zsig46 composition to a specific disease treatment, that includes Hirschsprung disease.

In response to Applicants' citation of (MPEP 2107.02 (IV)), Applicants' assertion of utility is on the basis of location of zsig46 gene to the close proximity of the genes linked to chromosome 13. It was stated in the previous office action and restated above that specification does not indicate any correlation of the role of a Zsig46 composition to a specific disease treatment or prevention associated with chromosome 13, like any other chromosome 13-linked genes may have. Therefore, this reason is sufficient for one skilled in the art to question the objective truth of the statement of utility.

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Applicants' comments regarding the utility guidelines set forth by "the PTO" for compliance with 35 U. S. C. 101; the current rules and regulations regarding the examination of patent applications as set forth by USPTO in "MPEP" have been used to assess the current application as required.

In the instant case, the failure of applicants to specifically identify why the claimed invention is believed to be useful renders the claimed invention deficient under 35 USC 101. No specific biological activity has been identified for the polynucleotide set forth in SEQ ID NO: 1, encoding a protein set forth in SEQ ID NO: 2 other than the fact that the protein may be secreted (p. 14-16). The person having ordinary skill in the art would not be able to identify any specific activity for the protein comprising or related to SEQ ID NO: 2 based on its structure alone for the reasons set forth above.

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 34-51 stand/are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention so that it would operate as intended without undue experimentation.

Conclusion

Claims 1-5 and 34-36 are rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

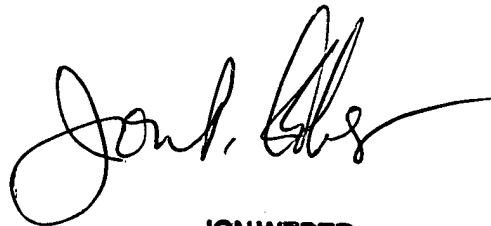
Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rita Mitra whose telephone number is (571) 272-0954. The Examiner can normally be reached from 9:30 a.m. to 6:30 p.m. on weekdays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Jon Weber, can be reached at (571) 272-0925. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (703) 872-9306. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0547.



Rita Mitra, Ph.D.

February 15, 2005

**JON WEBER**
SUPERVISORY PATENT EXAMINER